**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**TRENTON VICINAGE**

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| JANSSEN PHARMACEUTICALS, INC.,<br><br>*Plaintiff*,<br><br>v.<br><br>XAVIER BECERRA, Secretary of Health and Human Services, *et al.*,<br><br>*Defendants*. | Civil Action No. 23-cv-03818-ZNQ-JBD |

# MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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## INTRODUCTION

For decades, the United States has been the global leader in developing innovative medicines. As a result, patients in the United States have broader and faster access to cutting-edge treatments than patients in any other nation. This successful innovation ecosystem depends on a framework that combines legally protected exclusivity rights and market-based pricing, which together provide the necessary incentives for manufacturers to incur the enormous costs and risks of developing pioneering new medicines.

The Drug Price Negotiation Program (the "Program") established by the Inflation Reduction Act ("IRA")[1] strikes at the heart of that innovation ecosystem. The Program authorizes the Department of Health and Human Services ("HHS") to unilaterally impose punitive price controls for the most widely prescribed medicines in Medicare, including Janssen's Xarelto® products. In doing so, the IRA retroactively rescinds critical patent and regulatory exclusivity protections that fuel innovation, both today and over the long-term. These radical changes will impede development of new drugs, prevent further advancement of previously approved drugs (including new indications for patient populations with unmet medical needs),

[1] Pub. L. No. 117-169, §§ 11001–11004, 136 Stat. 1818, 1833–64 (2022) (codified in part at 42 U.S.C. §§ 1320f to 1320f-7).

and lead to reduced drug availability in the United States. All these outcomes harm patients.

The IRA compounds those flaws by using coercion and subterfuge to avoid accountability for the Program's devastating effects on innovation and patient access. According to the IRA, the Program involves a "negotiation" in which HHS and the manufacturer enter into an "agreement" to provide access to selected drugs at a "fair" price through Medicare. In reality, the "negotiation" is a charade. By design, manufacturers have no choice but to accept the prices dictated by HHS, which by statute must be well below market-based prices. Manufacturers may escape the Program's mandates only by (1) paying crippling penalties that greatly exceed the mandated price reduction (which in the case of Xarelto® would amount to *billions* of dollars in the first year alone); or (2) withdrawing *all* their products—not just the selected drug—from both Medicare and Medicaid, which together comprise nearly half the U.S. pharmaceutical market. Those provisions are the legal equivalent of a gun to the head. They would deprive Janssen of the resources necessary to continue competing and innovating, and they would also harm millions of patients, who would lose insurance coverage for the drugs they have come to depend on. These severe consequences for Janssen and the patients it serves leave Janssen with no viable choice but to submit to the Program's demands.

The Program violates Janssen's constitutional rights in at least three ways. *First*, it takes Janssen's property without just compensation in violation of the Fifth Amendment. The IRA compels Janssen to provide pharmacies and other Medicare participants "access" to Xarelto® on terms dictated by HHS and to which Janssen would never voluntarily agree. That forced transfer constitutes a physical taking by appropriating Janssen's property for the benefit of third parties. The fact that Janssen is paid *something* under the Program bears on the amount of just compensation due, but not on whether a taking has occurred in the first place.

*Second*, the Program violates Janssen's First Amendment right to refrain from speaking by compelling Janssen to endorse the Government's false narrative that its dictated prices for Xarelto® are "fair" and the result of a voluntary arm's-length "negotiation." The IRA compels Janssen to make these statements by requiring the company to sign what the statute describes as an "agreement" to comply with the Program's requirements. For good reason, Janssen views the IRA's compulsory representations as false and misleading because, in reality, Janssen must accept whatever terms HHS chooses to impose.

*Finally*, even if the Program could somehow be viewed as voluntary, it would still violate the unconstitutional conditions doctrine. The Government may not condition a manufacturer's continued participation in Medicare and Medicaid (for *all* of its products) on the manufacturer's surrender of constitutional rights with

respect to a single product. Nor can the Government condition participation in those federal programs on the manufacturer echoing the Government's preferred narrative about the Program.

The Court should declare that the Program violates the Takings Clause and First Amendment, and enjoin HHS from enforcing the provisions that violate Janssen's free speech rights, including any "agreement" Janssen is coerced into executing under those provisions.

## BACKGROUND

### I. Development of Innovative New Drugs Depends on a Robust Pharmaceutical Innovation Ecosystem.

The United States is the global leader in pharmaceutical development.[2] That position results from two key elements of the innovation ecosystem: (1) time-limited protections for new and expanded treatments, including patent rights and regulatory approvals that grant manufacturers exclusive rights over their innovative medicines, and (2) free-market pricing. Together, these elements create the incentives necessary for a pioneer drug developer to invest the billions of dollars and years of

[2] *See* David H. Crean, *Is the USA's Innovation Leadership Position At-Risk?*, Pharma Boardroom (Nov. 13, 2020), https://perma.cc/6R8M-UW8D (explaining that almost half of all medicines under development globally in 2020 were in the United States).

research required to bring an innovative drug to market,[3] a process that frequently results in failure.[4]

Patients are the ultimate beneficiaries of this market-based framework. Patients in the United States—particularly those with rare diseases and complex, difficult-to-treat medical conditions—have broader and faster access to innovative treatments than patients in any other country worldwide.[5] For their part, Janssen and its affiliates have invested more than $65 billion in pharmaceutical research and development since 2016, resulting in Food and Drug Administration ("FDA") approval for eight new medications and 52 additional indications or new product formulations to serve patient needs throughout the country.[6]

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[3] *See* Cong. Budget Off., *Research & Development in the Pharmaceutical Industry* (Apr. 2021), https://perma.cc/2ZC9-U2T3 (patent exclusivity rights "increas[e] drug companies' incentives to invest in R&D").

[4] See Tufts Center for the Study of Drug Dev., Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion (Nov. 18, 2014), https://perma.cc/XU5W-KPZ7; Joseph A. DiMasi et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20 (2016).

[5] See Doug Badger, Galen Inst., Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control Over Pricing and Restrictions on Access 15 (2019), https://perma.cc/8LFY-CAC4; Pharmaceutical Research and Manufacturers of America, Global Access to New Medicines Report 8, 11–26 (2023), https://perma.cc/PW8N-WEU8.

[6] *See* Declaration of Blasine Penkowski ("Penkowski Decl.") ¶¶ 4–5.

Medicare and Medicaid play a critical role in this innovation ecosystem. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023).[7] In 2021, Medicare accounted for 21% of the total U.S. pharmaceutical market, and Medicaid accounted for another 17%.[8] Manufacturers thus depend on the ability to offer their products through these critically important markets to develop the next generation of innovative drugs. Janssen and its affiliates, for example, market and sell 53 drugs in these federal programs, realizing approximately 40% of their total U.S. annual revenues from Medicare and Medicaid. For Janssen specifically, the importance of these federal markets is even more pronounced: it sells 21 drugs in these markets, with approximately 50% of the U.S. prescriptions filled for those products and approximately 65% of its 2022 gross revenues attributable to Medicare and Medicaid. *See* Penkowski Decl. ¶¶ 8–9. Participation in Medicare and Medicaid is crucial to Janssen's continued ability to fund pharmaceutical research and

[7] Medicare principally provides health insurance coverage for Americans ages 65 and above. 42 U.S.C. §§ 1395–1395*lll*. Medicare Part B provides health-insurance benefits for physician-administered drugs, among other things. *Id*. § 1395k. Medicare Part D provides health-insurance benefits for self-administered prescription drugs. Medicaid provides health insurance coverage for low-income Americans. *Id*. §§ 1396 to 1396w-7.

[8] Centers for Medicare and Medicaid Services ("CMS"), *NHE Fact Sheet*, https://perma.cc/M2QA-ZJJC (updated June 14, 2023).

development, compete with other manufacturers, and offer innovative treatments to the patients that need them. *See* Penkowski Decl. ¶¶ 11, 27.

Janssen's Xarelto® (rivaroxaban) is a direct result of the innovation ecosystem. FDA initially approved Xarelto® in 2011 to treat and help prevent blood clots and reduce the risk of stroke.[9] Over the next decade, Janssen continued to innovate to help patients with unmet medical needs. For example, Janssen has made additional investments to develop and obtain FDA approval for a lower strength dosage form in 2017 and four additional indications between 2018 and 2021—thus bringing the benefits of Xarelto® to new patient populations, including pediatric patients.[10] In 2022 alone, nearly 3 million patients filled close to 11 million Xarelto® prescriptions throughout the United States, with Medicare and Medicaid accounting for more than 60% of those prescriptions. *See* Penkowski Decl. ¶ 7.

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[9] *See* FDA, *FDA-Approved Drugs Listing for NDA 022406*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022406; FDA, *FDA-Approved Drugs Listing for NDA 202439*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202439.

[10] *See supra* note 9; FDA, *FDA-Approved Drugs Listing for NDA 215859*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215859.

## II. The IRA Dismantles the Market-Based Framework on Which Pharmaceutical Innovation Depends.

The IRA establishes a so-called "Drug Price Negotiation Program" that has four core steps. *See* 42 U.S.C. § 1320f. *First*, the IRA directs the Centers for Medicare and Medicaid Services ("CMS")[11] during the first year of the Program to identify the drugs that account for the highest Medicare Part D expenditures. *See id.* § 1320f-1(a)–(b). *Second*, CMS selects a subset of those drugs for participation in the Program. *Id.* *Third*, the IRA requires the manufacturer of a selected drug to sign an "agreement" to comply with the Program's terms and "negotiate" with the agency. *Id.* §§ 1320f-2(a), 1320f-3(a)(1). *Fourth*, CMS imposes a "maximum fair price" for the selected drug following the "negotiat[ion]" and requires the manufacturer to provide pharmacies and other Medicare participants "access" to the selected drug at that price. *Id.* §§ 1320f-2(a)(1)-(3), 1320f-3(a)(1), 1320f-4(a). Although the Program uses the language of negotiation and agreement, manufacturers like Janssen are actually compelled to submit and surrender their widely prescribed drugs on Government-imposed terms.

[11] The Secretary of HHS has delegated his statutory authority to administer the Program to CMS. *See* 88 Fed. Reg. 1390 (Jan. 10, 2023). Accordingly, this brief generally refers to CMS when discussing implementation of the Program.

### A. The IRA Compels Janssen to "Agree" to the Program's Requirements.

While the prices set by the Program do not go into effect until 2026, the Program's operations and impact begin in 2023. By September 1, 2023, CMS must select for the Program ten of the fifty drugs that account for the highest Medicare Part D expenditures. *See* 42 U.S.C. §§ 1320f(d)(1), 1320f-1(a)(1), (d); Declaration of Jeffery S. Chiesa ("Chiesa Decl.") Ex. A § 30.3 (explaining that CMS "will select" the top 10 drugs on that list for the Program's initial year). Based on the statutory criteria and Medicare expenditure data during the relevant time frame, *see* 42 U.S.C. §§ 1320f(d)(3)(A), 1320f-1(b)–(e), CMS will select Xarelto® for the 2026 initial price applicability year. *See* Penkowski Decl. ¶¶ 12–15.

Once CMS selects Xarelto®, Janssen will have only 30 days, until October 1, 2023, to sign a "Manufacturer Agreement" obligating Janssen to "negotiate" with CMS the "maximum fair price" Janssen may charge for the drug through Medicare. 42 U.S.C. §§ 1320(a)–(b), (d)(2)(A), 1320f-2. Contrary to the IRA's labels, the Program does not rest on a voluntary agreement. CMS has unilaterally drafted the Manufacturer Agreement and presented it to manufacturers on a take-it-or-leave-it basis. *See* Chiesa Decl. Ex. B. Janssen lacks any ability to alter or negotiate the Manufacturer Agreement's terms, and the IRA gives Janssen no viable choice but to sign that purported Agreement. What is more, CMS has included a provision in this "agreement" forcing Janssen to agree that CMS "retains authority to amend this

Agreement" even *after* Janssen is forced to sign—preemptively requiring agreement to unknown new terms that would trigger $1 million daily penalties for noncompliance. *See* Chiesa Decl. Ex. B § IV(b); *see also* 42 U.S.C. § 1320f-6(c).

If Janssen refuses to sign, it must pay an "excise tax" penalty on *every* domestic sale of Xarelto®—whether or not sold through Medicare—starting at 186% of the drug's daily U.S. sales and escalating to 1900% of sales.[12] 26 U.S.C. § 5000D(d); Chiesa Decl. Ex. D. These penalties far exceed the gross revenue Janssen receives for *total* U.S. Xarelto® sales in the federal and non-federal markets, and thus will exceed *any* possible price reduction under the Program. Specifically, the penalty would begin at more than $50 million per day, escalating to over $600 million per day after only nine months. *See* Penkowski Decl. ¶¶ 16–19. In the first year of noncompliance alone, Janssen's penalties would exceed $90 billion—an amount more than double the 2022 U.S. adjusted net earnings for *all* products sold by Janssen's ultimate parent company, Johnson & Johnson. *Id.* ¶ 20. Consistent with these staggering amounts, Congress recognized that no manufacturer could ever willingly incur these debilitating penalties when it estimated that nearly identical penalty provisions in a precursor bill would generate "no revenue." Chiesa Decl.

[12] Because the "excise tax" penalty is assessed on gross sales revenues, rather than net revenues, the penalty's actual economic burden on manufacturers is even more significant than the percentages listed above. *See* 26 U.S.C. § 5000D(a).

Ex. E; *see also id.* Ex. F at 10. Put simply, a manufacturer must give the Government what the Government demands under the Program, or pay far more in penalties.

Under the IRA, a manufacturer may escape from the Program's mandates and penalties only by withdrawing *all* of its products—not just the selected drug—from both Medicare and Medicaid. *See* 26 U.S.C. § 5000D(c); 42 U.S.C. §§ 1395-153(a)(1), 1396r-8(c). That purported choice is no choice at all. Medicare and Medicaid "dominat[e] the healthcare market" and represent "almost half the annual nationwide spending on prescription drugs." *Sanofi*, 58 F.4th at 699. The Government's control of such a large market share confers substantial market power. *See, e.g.*, *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 26–29 (1984). Completely withdrawing from almost half the domestic pharmaceutical market is not commercially feasible. Doing so would deprive Janssen of half the U.S. prescriptions filled for its drug products and approximately 65% of its gross revenues—revenues it needs to compete in the marketplace and develop next-generation treatments over the long-term. Penkowski Decl. ¶¶ 9, 21–22, 27. Withdrawal would also put at risk millions of patients who depend on Janssen's products to treat serious medical conditions. *Id.* To illustrate, had Janssen not been able to participate in Medicare and Medicaid in 2022, patients would have lost this insurance coverage for millions of Xarelto® prescriptions along with prescriptions

for the other 19 drugs Janssen markets through Medicare and Medicaid. *See id.* ¶¶ 7–8.

Even if withdrawing from Medicare and Medicaid were a viable option, it would not avoid the IRA's exorbitant penalties. If Janssen were to attempt to withdraw now, the IRA would prohibit Janssen from exiting Medicare and Medicaid until January 2025, meaning that every domestic sale of Xarelto® would be penalized for at least 15 months—reaching a daily 1900% penalty during the last six months of that period. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii). Even if Janssen had begun the withdrawal process the moment the IRA was enacted in August 2022, it would *still* have been subject to the penalties until January 2024. *See id.* Janssen thus would have been forced to pay 186% of every domestic sale of Xarelto® in penalties for the last quarter of 2023. *See* 26 U.S.C. § 5000D.[13]

[13] After several lawsuits were filed challenging the constitutionality of the Program, CMS issued guidance on June 30, 2023, suggesting that a manufacturer could withdraw from Medicare and Medicaid faster than the statute allows. *See* Chiesa Decl. Ex. A § 40.6. This effort to make the Program appear less punitive does not comport with the statute. The IRA suspends the excise tax penalty when CMS receives notice of the *manufacturer's* termination of its Medicare and Medicaid agreements. 26 U.S.C. § 5000D(c)(1). Consonantly, the IRA's withdrawal timelines discussed above are triggered by "[a] *manufacturer* … terminat[ing] an agreement." 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (emphasis added). The CMS guidance would ignore these provisions and treat a manufacturer's termination as if it were a termination "[b]y the Secretary" with its conveniently shorter withdrawal timeline. *See id.* § 1395w-114a(b)(4)(B)(i); *see also* Chiesa Decl. Ex. A § 40.6. CMS cannot rewrite the statutory timeline to suit its litigating position.

### B. The Program Uses the Language of "Negotiation" to Cloak the Compelled Surrender of Drug Products on Government-Imposed Terms.

After Janssen is forced to sign the Manufacturer Agreement, it will be compelled to submit detailed and highly confidential business information to CMS by October 2, 2023. 42 U.S.C. §§ 1320f(d)(5)(A), 1320f-2(a)(4), 1320f-3(b)(2). Every day of noncompliance with that burdensome duty would result in a civil monetary penalty of $1 million. *Id*. § 1320f-6(c).

Following these submissions, the so-called "negotiation" begins with CMS making an initial "offer" and Janssen making a "counteroffer." *Id*. § 1320f-3(b)(2)(B)–(D). CMS then "respond[s] in writing," *id*. § 1320f-3(b)(D), with the final "maximum fair price," *id*. §§ 1320f(d)(5)–(6), 1320f-4(a)(1). CMS has attempted to make this arrangement appear more like a genuine "negotiation" by declining to impose the "maximum fair price" unless the manufacturer executes a supplemental "agreement" adopting it. *See* Chiesa Decl. Ex. A § 60.6. As with the initial Manufacturer Agreement, however, the reality is that Janssen has no viable choice but to accept the CMS price. Failing to do so would subject Janssen to the same debilitating "excise tax" penalties or Medicare and Medicaid withdrawal consequences that forced it to sign the Manufacturer Agreement in the first place. *See* 26 U.S.C. § 5000D(a). The "negotiation," by design, can end in only one way:

with the Government dictating the price it will pay. *See* 42 U.S.C. § 1320f-3(b)(2)(E).

The IRA calls this price that the Government selects the "maximum fair price" for the selected drug. *Id.* §§ 1320f-3, 1320f-4. The IRA imposes a statutory ceiling on what that price can be. That ceiling must be the lesser of (1) what Medicare Part D and Medicare Advantage plans pay for the drug (net of all rebates) or (2) a percentage of the price wholesalers pay for the drug. Under the latter approach, the "maximum fair price" must be at least 25–60% below the average price paid by non-federal wholesalers, depending on how long the selected drug has been on the market. *Id*. § 1320f-3(c). For example, because Xarelto® was first approved by FDA in 2011, CMS must select a "maximum fair price" that is at least 25% below the benchmark, market-based price paid by non-federal wholesalers. *See* 42 U.S.C. § 1320f-3(c)(3)–(5).

Under either approach to the statutory ceiling amount, the IRA requires CMS to "achieve the *lowest* maximum fair price for each selected drug" below that statutory ceiling. *Id*. § 1320f-3(b)(1) (emphasis added). Because the IRA does not prescribe a pricing floor (with an exception not relevant here), it allows CMS—the same agency that pays for selected drugs through Medicare—to impose a nominal price for Xarelto® products (all the way down to $0), regardless of their market value or Janssen's patent rights. *See* ECF 1, ¶¶ 32, 91–92; *see also* Chiesa Decl. Ex. G at

3 (CMS Administrator Brooks-LaSure testimony stating that CMS will "leverag[e] [its] new authority under the IRA" "to lower drug costs"); *id.* Ex. F at 11 (Congressional Budget Office study concluding that drug prices "will decrease by roughly 50 percent, on average, as a result of" the Program).

The "maximum fair price" becomes effective on January 1, 2026. *See* 42 U.S.C. §§ 1320f(d), 1320f-2(a). Janssen will then be obligated—under threat of civil monetary penalties ten times the difference between the price charged and the "maximum fair price," *id*. § 1320f-6d(a)—to grant Medicare participants "access" to Xarelto® at the latter, CMS-dictated price and other terms imposed unilaterally by the agency. *Id*. § 1320f-2(a). That access requirement continues indefinitely, until CMS "determines" that a generic version of the drug is "approved" and "marketed." *Id*. § 1320f-1(c)(1).

## LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Courts regularly resolve pre-enforcement constitutional challenges to federal statutes through summary judgment. *See, e.g.*, *General Electric Co. v. EPA*, 360 F.3d 188, 189 (D.C. Cir. 2004).

## ARGUMENT

### I. The Program Violates the Fifth Amendment by Appropriating Janssen's Property.

Behind the false rhetoric of "negotiation," the Program imposes a Government-mandated transfer of property—Janssen's Xarelto® products—at a Government-determined price. This scheme constitutes a physical taking under the Fifth Amendment, entitling Janssen to the fair market value of the appropriated property. Yet the IRA caps a manufacturer's compensation and requires CMS to decrease that compensation well below market-based prices, in violation of the Takings Clause's just-compensation requirement. The Court should therefore issue a declaratory judgment that the Program violates the Fifth Amendment.

#### A. The Program Effects a Physical Taking of Janssen's Xarelto® Products.

The Takings Clause of the Fifth Amendment embodies the commonsense notion that "people … do not expect their property, real or personal, to be actually occupied or taken away." *Horne v. Dep't of Agric.*, 576 U.S. 350, 361 (2015). By preventing "private property" from being "taken" by the Federal Government "without just compensation," U.S. Const., amend. V, the Takings Clause "preserve[s] freedom and empowers persons to shape and to plan their own destiny" rather than letting the Government "do so for them," *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071 (2021) (cleaned up).

These protections extend to personal property. *See Horne*, 576 U.S. at 359 ("Nothing … suggests that personal property [i]s any less protected against physical appropriation than real property"). Janssen's Xarelto® products—i.e., the pills and their packaging—are personal property.[14] Janssen thus enjoys the full bundle of rights associated with ownership, including "rights to possess, use and dispose of" its drug products. *Horne*, 576 U.S. at 360. "[T]he most essential stic[k]" in this bundle of rights is "the right to exclude others" from accessing Janssen's property. *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979); *accord Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982).[15]

When the Government deprives an individual of any one of these rights "for itself or a third party," it inflicts a physical taking, and the Fifth Amendment imposes a "simple, *per se* rule: The government must pay for what it takes." *Cedar Point*, 141 S. Ct. at 2071.[16] *Horne* and *Cedar Point* are illustrative.

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[14] Janssen's property rights encompass all formulations of its Xarelto® products, including its pill and oral suspension (i.e., liquid) forms.

[15] Janssen alleges a taking of its drug products. ECF 1 ¶ 93. While Janssen has additional property rights in Xarelto®, *id.* ¶¶ 91–92, Janssen is not alleging a taking of those separate rights here. That said, these additional rights augment Janssen's common law right to exclude.

[16] Courts conduct a separate inquiry for so-called "regulatory takings"—situations where, "rather than appropriating private property for itself or a third party, [the Government] instead imposes regulations that restrict an owner's ability to use his own property." *Cedar Point*, 141 S. Ct. at 2071–72.

In *Horne*, federal law forced raisin growers to transfer a portion of their crops "to the Government, free of charge." 576 U.S. at 355. That forced transfer was a physical taking because the "[r]aisin growers … los[t]" core "property rights in the appropriated raisins" and could no longer possess, use, or dispose of the raisins as they wished—the challenged federal program involved an "actual taking of possession and control." *Id.* at 362.

In *Cedar Point*, the Court likewise found a physical taking where the challenged law had given union organizers a "right of access … to the premises of an agricultural employer," over the property owner's objection. 141 S. Ct. at 2069. This too was a physical taking because the Government had stripped property owners of their "right to exclude" by granting third parties an entitlement to access the property against the employer's will. *Id.* at 2072–74.

The Program similarly strips Janssen of its property rights in its Xarelto® products. The Program grants third parties a right to access Janssen's Xarelto® products and forces Janssen to transfer the products to those third parties. The physical taking results from the combined effect of three aspects of the Program: (1) the access provision, (2) the formulary inclusion requirement, and (3) the noncompliance penalties.

*First*, once CMS selects Xarelto® for the Program, Janssen will be compelled to sign the Manufacturer Agreement. *See* 42 U.S.C. § 1320f-2(a). This Agreement

obligates Janssen to provide "*access* to the maximum fair price … with respect to such a selected drug" to individuals enrolled in a Medicare Part D plan, along with those individuals' pharmacies and other dispensing providers. *Id.* §§ 1320f(c)(2)(A), 1320f-2(a)(3) (emphasis added). The IRA thus strips Janssen of its constitutionally protected property rights by granting third parties a right to access Janssen's drug products on Government-dictated terms.

*Second*, the IRA requires every Part D prescription drug insurance plan formulary to include the selected Part D drugs. *Id.* § 1395w-104(b)(3)(I).[17] This provision facilitates third parties' statutory access right: by mandating a selected drug's inclusion on every Part D formulary, the IRA ensures that every plan enrollee—the same group of individuals the IRA provides with a right of access, *see id.* §§ 1320f(c)(2)(A), 1320f-2(a)(3)—will receive Part D coverage for the selected drug. Additionally, the formulary inclusion requirement will deprive the manufacturer of its right to control how third parties access its property: Before the IRA was enacted, a manufacturer could determine through negotiation whether, and on what terms, its drugs would be included on a Part D plan's formulary. Now, a

[17] A Part D formulary is a list of drugs covered by a Medicare Part D insurance plan. CMS oversees these lists and sets certain minimum requirements. *See* 42 U.S.C. § 1395w-104(b)(3); 42 C.F.R. § 423.120(b). Relevant to this case, a Part D plan generally provides coverage to its enrollees only for drugs listed on its formulary.

manufacturer's drug will be included on every Part D plan and made subject to CMS's unilaterally imposed terms.

*Third*, the IRA threatens immense penalties at every step of the Program as a means of ensuring that manufacturers acquiesce in the forced transfer of their property. At the drug selection phase, failing to sign the Manufacturer Agreement and grant third-party access to the selected drug triggers daily penalties that far exceed the manufacturer's revenue on all domestic sales of the selected drug (and would quickly exceed the annual adjusted net U.S. earnings of Janssen's parent company for *all* of its products, *see* Penkowski Decl. ¶ 20). 26 U.S.C. § 5000D. And once CMS sets what it deems the "maximum fair price," manufacturers are subject to additional civil monetary penalties of ten times any amount they charge above the CMS-dictated price. 42 U.S.C. § 1320f-6(a).

Viewed as a whole, the IRA grants third parties the right to "access … [Janssen's] property," *Cedar Point*, 141 S. Ct. at 2074, and "actual[ly] tak[e] … possession and control" of Janssen's products, *Horne*, 576 U.S. at 362. In doing so, the IRA "abrogat[es] [Janssen's] right to exclude," *Cedar Point*, 141 S. Ct. at 2074, compels the "[a]ctual … transfer" of drugs from Janssen to third parties, and strips Janssen of "any right to control [the] disposition" of its products, *Horne*, 576 U.S. at 361, 364. Although cloaked as a "negotiation," the Program is a physical taking no matter how it "comes garbed," *Cedar Point*, 141 S. Ct. at 2072.

To be sure, the Government has repeatedly characterized the Program as "voluntary." *See* ECF 1 ¶ 58. But the IRA makes clear that manufacturers who do not submit to the Program's requirements must pay crippling daily penalties on every domestic sale of the selected drug, well in excess of even a 100% price reduction on sales through Medicare. *See supra* pp. 9–10.[18] The penalties are designed to be so ruinous that no manufacturer could take this route—even Congress has conceded that no manufacturer would ever pay these penalties.[19] Moreover, the only way to avoid the penalties is to withdraw all of the manufacturer's products from Medicare and Medicaid, which is not viable for the reasons described above. *See id.* Nor is withdrawal what the Government wants. It *needs* manufacturers to submit to the Program and remain in Medicare and Medicaid, otherwise the nation's most widely prescribed drugs would be unavailable to nearly half of U.S. patients. It would defeat Congress's purpose—and the Government's public message in promoting the IRA—if those necessary treatments were withdrawn from Medicare and Medicaid. Forced withdrawal would also strip patients of insurance coverage for important

[18] Although denoted a "tax," the IRA's penalties are not imposed broadly, but rather on a narrow and select group of drug manufacturers for the sole purpose of coercing those manufacturers into submitting to the Program's terms.

[19] *See* Chiesa Decl. Ex. E at 8 (similar provisions would raise no revenue); Chiesa Decl. Ex. F at 10 ("manufacturers will comply with the negotiation process because the costs of not doing so" would be too great); *see also* Chiesa Decl. Ex. A § 40.1 (presenting manufacturers' "options" as including only Program participation or total Medicare and Medicaid withdrawal).

medicines. Instead, Congress offered illusory paths designed to make the Program appear voluntary, but those paths are untenable for actual use.

In any event, even a less punitive penalty would not change the takings analysis. In *Horne*, for example, the raisin growers could have chosen to pay a "civil penalty" for not complying with the Government's requirements, or they could have left the raisin market entirely by "planting different crops." 576 U.S. at 356, 357. But, the Court held that, despite these ostensible "choices," a taking still occurred: the Government could not "hold hostage" growers' ability to sell "produce in interstate commerce" with a ransom to "forfei[t] the right to compensation" for a physical taking. *Id.* at 365–66. The same is true here. But for the IRA's "gun to the head," *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581 (2012) ("*NFIB*") (concluding that the States had no "real option but to acquiesce" to Affordable Care Act), Janssen would not participate in the Program and be forced to transfer its Xarelto® products to those with a statutory access right. *See* Penkowski Decl. ¶ 22. As the Supreme Court has long recognized, the Government cannot "impose an unconstitutional burden" on private parties "by the threat of penalties … and then … declare the acceptance [of that burden] voluntary." *Union Pac. R. Co. v. Pub. Serv. Comm'n of Mo.*, 248 U.S. 67, 70 (1918).

### B. The Program's Government-Dictated Compensation is Constitutionally Inadequate.

A physical taking triggers the Government's "categorical duty to pay just compensation." *Horne*, 576 U.S. at 358. That the Program provides *some* compensation to manufacturers does not negate the fact that it effects a physical taking, *see id.* at 364, or evade the requirement of just compensation. Under the Fifth Amendment "just compensation" is "measured by the market value of the property at the time of the taking." *United States v. 50 Acres of Land*, 469 U.S. 24, 29 (1984); *accord Horne*, 576 U.S. at 366–69. There is no question that CMS's selected prices will not satisfy this standard. By statutory directive, they will not.

The IRA sets a mandatory price ceiling for selected drugs. 42 U.S.C. § 1320f-3(c). This price must be *at least* 25% below the average price non-federal wholesalers pay for the selected drug. *See id.* § 1320f-3(c)(1)(C). And in some cases, that ceiling must be even lower, set at what Medicare Part D and Medicare Advantage plans pay for the drug net of all rebates. *See id.* § 1320f-3(c)(1)(B)(i). No matter which amount the IRA designates as the *highest* permissible price, CMS remains under the same mandate: to "achieve the *lowest*" possible price below the ceiling, with no statutory floor. *See id.* § 1320f-3(b)(1). Whatever price CMS dictates for Janssen's Xarelto® products, the IRA's price ceiling, CMS's mandate, and the statute's core purpose ensure that any compensation Janssen receives for each taking will *always* be below the product's market value.

### C. Declaratory Relief is Appropriate.

Because the Program effects a physical taking without just compensation, declaratory relief is appropriate. The Court has discretion to "declare the rights and other legal relations of any interested party seeking such declaration" when "appropriate." 28 U.S.C. § 2201. Four factors inform the Court's inquiry: (1) whether declaratory relief "will resolve the uncertainty … which gave rise to the controversy"; (2) "the convenience of the parties"; (3) "the public interest in the settlement of the uncertainty"; and (4) "the availability and relative convenience of other remedies." *Terra Nova Ins. Co. Ltd. v. 900 Bar, Inc.*, 887 F.2d 1213, 1224 (3d Cir. 1989) (cleaned up).

In this case, all four factors warrant declaratory relief. *First*, the Program results in a physical taking, and absent declaratory relief the Government will be required to pay manufacturers just compensation for every selected drug product transferred to a third party under the Program. *Second*, a declaratory judgment issued before the Program goes into effect will apprise the Government of its constitutional obligation to pay just compensation and affirm Janssen's constitutional rights in its property. *Third*, "neither the government nor the public itself can claim an interest in enforcing an unconstitutional statute. The public interest generally favors such constitutional protection[.]" *LCN Enters., Inc. v. City of Ashbury Park*, 197 F. Supp. 2d 141, 154 (D.N.J. 2002) (cleaned up); *accord*

*Amalgamated Transit Union Local 85 v. Port Auth. of Allegheny Cnty.*, 39 F.4th 95, 109 (3d Cir. 2022). Resolution of these issues also furthers the public interest because the Program threatens to cripple innovation and patient access to new and expanded treatments. *See supra* pp. 4–13.

*Fourth*, the Declaratory Judgment Act and Supreme Court precedent support the conclusion that a claim for declaratory relief is an appropriate means of resolving questions about the Program's constitutionality. By statute, declaratory relief is available "whether or not further relief is or could be sought," 28 U.S.C. § 2201(a), and the Supreme Court has declared a property owner's rights with respect to a takings claim before a taking has occurred, *see Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 998, 1013 (1984) (holding, in a suit that sought "declaratory relief," that an agency's disclosure of trade secrets "will constitute a taking" if the trade secrets were submitted to the agency subject to a promise of confidential treatment).[20]

In addition, "equitable relief" is available here because "an adequate provision for obtaining just compensation [does not] exist." *Knick*, 139 S. Ct. at 2176. While

[20] Even if the Government contends that "equitable relief" is available with respect to a takings claim only when "an adequate provision for obtaining just compensation [does not] exist," *Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2176 (2019), that principle does not apply to claims for declaratory relief. *Knick* addressed "requests for *injunctive* relief," 139 S. Ct. at 2175 (emphasis added), but did not analyze claims for declaratory relief—which as noted above is available "whether or not further relief is or could be sought," 28 U.S.C. § 2201(a). Even if the *Knick* test did apply here, it is satisfied for the reasons given below.

Xarelto® is subject to the Program, "the Act authorizes a repetitive (and essentially endless) series of new, *per se* takings." *PhRMA v. Williams*, 64 F.4th 932, 942 (8th Cir. 2023). Without declaratory relief, Janssen would be consigned to "repeatedly bring new suits to obtain just compensation" every time it is forced to transfer a single dose of Xarelto®. *Id.*

But "[f]orcing a party to engage in repetitive lawsuits" that "all gro[w] out of the one wrongful act and involv[e] similar questions of fact and law" are "precisely the sort of legal inadequacy that would make equitable relief an available and preferred method of redress." *Id.* (cleaned up); *accord Di Giovanni v. Camden Fire Ins. Ass'n*, 296 U.S. 64, 70 (1935) ("Avoidance of the burden of numerous suits at law between the same or different parties, where the issues are substantially the same, is a recognized ground for equitable relief in the federal courts."). Instead, declaratory relief "allows individuals threatened with a taking to seek a declaration of the constitutionality of the disputed governmental action before potentially uncompensable damages are sustained." *Duke Power Co. v. Carolina Env't Study Grp.*, 438 U.S. 59, 71 n.15 (1978). Declaratory relief is thus appropriate here.

Because all four factors support declaratory relief, the Court should declare that the Program effects a taking of Janssen's Xarelto® products.

## II. The IRA Violates the First Amendment By Compelling Manufacturers to Endorse the Government's Message that the Program Involves Negotiating Fair Prices for Selected Drugs.

As explained above, the IRA compels manufacturers to provide access to selected products at a price determined by the Government. *See supra*, pp. 9–11, 20–22. Because such regimes are politically unpopular,[21] the IRA seeks to portray the Program as involving voluntary "agreement[s]" to "negotiat[e]" "fair" prices. *See, e.g.*, 42 U.S.C. §§ 1320f-1(a), 1320f-2(a)(1)-(3), 1320f-3(a)(1), 1320f-4(a).

Other Government statements echo this narrative. The President has said that the Program merely "giv[es] Medicare the power to *negotiate* drug prices,"[22] and the CMS Administrator has likewise stated that the Program "is a voluntary process for manufacturers to negotiate with us directly."[23]

After CMS selects Xarelto® for the Program by September 1, 2023, Janssen will be compelled to endorse this political messaging by signing an "agreement" to

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[21] *Compare* National Tracking Poll #2109099, at 13, Morning Consult (Sept. 16–19, 2021), https://perma.cc/9XCL-JECJ (American public supports "allowing the federal government to directly negotiate with drug companies to get a lower price on medications"); *with id*. at 17 (less than half of Americans support "effectively allowing the federal government to set the prices of drugs.").

[22] State of the Union Address (Feb. 7, 2023) (emphasis added). *See also* Remarks by Pres. Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022) ("Medicare will finally get the power to negotiate lower prescription drug prices.").

[23] Michael Erman & Patrick Wingrove, *U.S. Will Allow Drugmakers to Discuss Medicare Drug Price Negotiations*, Reuters (June 30, 2023), https://perma.cc/5CRE-KGXQ.

enter a "negotiation" regarding a "maximum fair price." Yet Janssen disagrees with each of these statements and will be forced to express "support for views [it] find[s] objectionable." *Janus v. Am. Fed'n of State, Cnty. & Mun. Emps. Council 31*, 138 S. Ct. 2448, 2463 (2018). By compelling Janssen to convey the Government's preferred messages, the IRA fails First Amendment scrutiny.

### A. Compelled Speech Burdens First Amendment Rights and Must Satisfy the "Most Exacting" Scrutiny.

"At the heart of the First Amendment lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994). For this reason, "freedom of speech includes both the right to speak freely and the right to refrain from speaking at all." *Janus*, 138 S. Ct. at 2463; *accord 303 Creative LLC v. Elenis*, 143 S. Ct. 2298, 2322 (2023) ("[A]ll persons are free to think and speak as they wish, not as the government demands."). "Government action that requires stating a particular message favored by the government [thus] violates the First Amendment right to refrain from speaking." *Miller v. Mitchell*, 598 F.3d 139, 151 (3d Cir. 2010); *accord Janus*, 138 S. Ct. at 2463; *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 573 (1995).

While Government restrictions on speech are disfavored, compelled speech causes "additional damage" because the speakers "are coerced into betraying their convictions." *Janus*, 138 S. Ct. at 2464. Indeed, "[m]andating speech that a speaker

would not otherwise make necessarily alters the content of the speech," and accordingly reflects "a content-based regulation of speech." *Riley v. Nat'l Fed. of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988); *accord Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371 (2018) ("*NIFLA*").

Accordingly, governmental attempts to "compel speakers to utter or distribute speech bearing a particular message" violate the First Amendment unless they satisfy "the most exacting scrutiny." *Turner*, 512 U.S. at 642. Such mandates are invalid unless they are "a narrowly tailored means of serving a compelling [governmental] interest." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 17, 19 (1986) ("*PG&E*"); *see Riley*, 487 U.S. at 798. Because the IRA compels Janssen to convey messages with which it disagrees—and because the Government has no legitimate interest (much less a compelling one) in forcing Janssen to engage in that misleading speech—the Program violates the First Amendment.

### B. The IRA Compels Janssen to Endorse Misleading Government Messages on a Matter of Public Concern.

When the government selects Xarelto® for participation in the Program, Janssen will be compelled to sign a written "agreement" to "negotiate" a "maximum fair price." But Janssen does not believe that there is any real agreement or negotiation, and it strongly disagrees that the government-imposed price for Xarelto® will be "fair." The Program thus "compel[s] affirmance of a belief with

which [Janssen] disagrees" and would never otherwise express, in violation of the First Amendment. *Hurley*, 515 U.S. at 573; *see also, e.g.*, *PG&E*, 475 U.S. at 17.

*First*, Janssen would communicate that it has *voluntarily* agreed to the Program's terms. *See* 42 U.S.C. § 1320f-2(a); Chiesa Decl. Ex. B at 1 (stating the manufacturer "on its own behalf ... hereby agree[s] to the following"). Janssen disagrees with this message and does not wish to endorse it. Rather, Janssen intends to sign only because it has no viable alternative. *See supra* p. 9–11; Penkowski Decl. ¶¶ 22, 24. Nor would Janssen call the document it is forced to sign an "agreement," because Janssen does not agree with its terms. Penkowski Decl. ¶¶ 23, 26.

Indeed, in the Manufacturer Agreement—which CMS drafted and will present to Janssen on a take-it-or-leave-it basis—CMS granted itself the power to unilaterally change the terms of the purported "Agreement" as it deems necessary even *after* Janssen has signed. *See* Chiesa Decl. Ex. B §§ II(e), IV(b). Failure to comply with these new terms would, according to CMS, trigger a $1 million per day civil monetary penalty. *See* Chiesa Decl. Ex. A § 100.2. To call such a one-sided document an "agreement" strains the English language past the breaking point.

*Second*, Janssen would communicate that the Program involves a "negotiation" that would result in Janssen and CMS "agreeing" on a price for Xarelto®. *See, e.g.*, Chiesa Decl. Ex. B at 1 (underscoring the manufacturer's purported ability to "reac[h] agreement with CMS"); *id.* § II(a) (stating "CMS and

the Manufacturer agree ... to negotiate to determine ... a maximum fair price for the Selected Drug"); *id.* add. 1 (explaining "the Manufacturer and CMS have engaged in negotiation" and "now agree to a price"). Again, Janssen disagrees with this message and does not wish to endorse it. Echoing the political rhetoric accompanying the IRA, that message conveys the impression of an actual arms-length contract negotiation. *See* 42 U.S.C. § 1320f-2(a); Chiesa Decl. Ex. A at 28; *id.* Ex. B, § II(a) & add. 1. A real negotiation produces a binding contract only when both parties freely agree on its terms, especially price. Yet here, Janssen considers the "negotiations" to be a sham, devoid of any attributes of a real negotiation. *See* Penkowski Decl. ¶¶ 24, 26.

The Manufacturer Agreement confirms the point—manufacturers will not negotiate any terms of the "agreement" because CMS has acted as a regulator (not a contracting counter-party) and already announced all the terms, with no input from the purported counter-parties to the agreement. The Manufacturer Agreement simply leaves a blank for the price in an addendum, which CMS will fill in with whatever price it chooses. *See* Chiesa Decl. Ex. B add. 1. Once CMS takes that step, Janssen will be forced to sign the addendum, face crippling "excise tax" penalties, or withdraw from Medicare and Medicaid entirely. That process is a far cry from an actual "negotiation."

*Third*, Janssen would communicate that the CMS-dictated price is "fair." *See, e.g.*, *id.* § II(a), (c), add. 1. Janssen disagrees with this message because, in its view, the Program is specifically designed to impose unfair prices. Penkowski Decl. ¶¶ 25–26. The Program disregards market value—the accepted metric for determining a "fair" price, *see Horne*, 576 U.S. at 368–70—by obligating CMS to set prices well below market-based prices. 42 U.S.C. §§ 1320f-3(c), 1320f-3(b)(1).

CMS has responded to litigation challenging the constitutionality of the IRA by inserting the following disclaimer in the Manufacturer Agreement:

> In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug.

Chiesa Decl. Ex. B § IV(f). But the disclaimer does not cure the First Amendment violation because it does not expunge Janssen's signature, which publicly conveys the message that the signer endorses the content of the Manufacturer Agreement and the statutory scheme the Agreement implements.

The Supreme Court has explained that it would "plainly violat[e]" the First Amendment for the government to require individuals "to sign a document expressing support for a particular set of positions on controversial public issues." *Janus*, 138 S. Ct. at 2464; *see also John Doe No. 1. v. Reed*, 561 U.S. 186, 194–95 (2010) (rejecting argument that "signing a petition … does not involve any

significant expressive element"). The same is true here. Indeed, the Manufacturer Agreement expressly states that, by signing, a manufacturer "hereby agree[s]" to everything contained in the Agreement. Chiesa Decl. Ex. B at 1 & § II; *see also*, *e.g.*, *Raiczyk v. Ocean Cnty. Vet. Hosp.*, 377 F.3d 266, 270 (3d Cir. 2004) ("[I]t is well settled that signing a contract creates a conclusive presumption that the signer read, understood, and assented to its terms." (cleaned up)).

Moreover, a disclaimer does not alter the First Amendment analysis because such a maneuver "would justify any law compelling speech." *Masterpiece Cakeshop, Ltd. v. Colo. Civ. Rights Comm'n*, 138 S. Ct. 1719, 1745 (2018) (Thomas, J., concurring in part and concurring in the judgment). Rather, leaving the compelled speaker free separately to disclaim a compelled viewpoint simply "begs the core question." *Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241, 256 (1974); *see also Masterpiece Cakeshop*, 138 S. Ct. at 1745. In short, the disclaimer "does not suffice" to comply with the First Amendment because the government cannot "require speakers to affirm in one breath that which they deny in the next." *PG&E*, 475 U.S. at 15 nn.11 & 16 (plurality op.).

### C. The IRA's Compelled Speech is Not Narrowly Tailored to Serve a Compelling Government Interest.

By compelling Janssen to sign the Manufacturer Agreement, the IRA forces Janssen to be a "vehicle for spreading a message with which it disagrees." *PG&E*, 475 U.S. at 17. That extraordinary step is permissible only if the compelled speech

is "a narrowly tailored means of serving a compelling [governmental] interest." *Id.* at 19; *see Turner*, 512 U.S. at 642; *Reed v. Town of Gilbert*, 576 U.S. 155, 171 (2015). The Program fails both parts of that demanding test.[24]

The Government has no interest—let alone a compelling one—in compelling manufacturers to amplify the Government's political message. Nor does the Government have a compelling interest in deceiving the public regarding the nature of the Program. To the contrary, government regulation of speech is typically restricted to preventing deceptive or misleading public statements, not furthering them. *Compare Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771–72 (1976) (government may properly regulate "deceptive or misleading" commercial speech), *with Turner*, 512 U.S. at 641 (government may not "manipulat[e] the public debate through coercion rather than persuasion").

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[24] Although the Program touches on the commercial sphere, it does not compel "commercial speech," which is speech that "does no more than propose a commercial transaction." *Harris v. Quinn*, 573 U.S. 616, 648 (2014) (quotation omitted); *see also*, *e.g.*, *United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001) (same). Viewing the compelled speech "as a whole," *Riley*, 487 U.S. at 796, the Program directs Janssen to endorse the politically palatable fiction that manufacturers are voluntarily engaged in a market "negotiation" with the government. The Program's mandates must therefore satisfy the "test for fully protected expression." *Riley*, 487 U.S. at 796. Even were the Program's compelled speech purely "commercial," it would still be subject to "exacting scrutiny" that likewise requires "a compelling state interest that cannot be achieved through means significantly less restrictive of associational freedoms." *Janus*, 138 S. Ct. at 2464 (quotation omitted). The IRA cannot satisfy this "exacting" review for the same reasons that its fails strict scrutiny.

To the extent that Congress's goal of reducing drug prices is a compelling public interest, requiring manufacturers to make public statements regarding the Program's voluntariness, the nature of the negotiations, and the fairness of the resulting price does not further that goal. *See* 42 U.S.C. § 1320f-3(b)(1). Far from being "narrowly tailored" to reduce prices, the Program could exist without the manufacturers being forced to convey these messages. *See PG&E*, 475 U.S. at 17 (compelled-speech mandate must be narrowly tailored); *Turner*, 512 U.S. at 642 (same). All the IRA's structure and terminology does is adorn the Program in a cloak of feigned cooperation to avoid the political backlash that would follow from the Government acknowledging its efforts to unilaterally impose its own selected prices—at the expense of patients and future pharmaceutical innovation. The First Amendment forbids this compelled endorsement of the Program's sleight-of-hand.

**D. Injunctive Relief is Warranted.**

Janssen will be compelled to sign the Manufacturer Agreement by October 1, 2023, creating an obligation for Janssen to "negotiate" a "maximum fair price" for Xarelto®. Because violations of the First Amendment "unquestionably constitut[e] irreparable injury," an injunction is warranted. *Elrod v. Burns*, 427 U.S. 347, 373 (1976). Indeed, courts routinely award injunctive relief in compelled speech cases. *See, e.g.*, *NIFLA*, 138 S. Ct. at 2370; *Riley*, 487 U.S. at 787, 803; *Wooley v. Maynard*,

430 U.S. 705, 712, 717 (1977); *Miller v. Skumanick*, 605 F. Supp. 2d 634, 646–47 (M.D. Pa. 2009) (entering temporary restraining order regarding compelled speech).

Accordingly, the Court should enjoin Defendants from compelling Janssen to sign the Manufacturer Agreement. If, however, Janssen is compelled to sign the Manufacturer Agreement before the Court resolves this case, the Court should declare the agreement void and enjoin Defendants from enforcing its terms—or the Program's corresponding penalties—against Janssen.

## III. Even if the Program Were Voluntary, It Would Still Impose Unconstitutional Conditions on Janssen's Participation in Medicare and Medicaid.

For the reasons explained above, the "voluntary" aspects of the Program are illusory. Congress designed the Program to yield only one outcome: Janssen signing the Manufacturer Agreement and submitting to the Government's demands.

But even if the Program could be made "voluntary," it would still be unconstitutional. Because "the government may not deny a benefit to a person because he exercises a constitutional right," *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (cleaned up), the Program cannot condition Janssen's participation in Medicare and Medicaid on Janssen's relinquishment of its constitutional rights.

This protection—known as the unconstitutional conditions doctrine—applies even when a person "has no right to a valuable governmental benefit." *Perry v.*

*Sindermann*, 408 U.S. 593, 597 (1972). And it precludes the Government from "produc[ing] a result which it could not command directly." *Id.* (cleaned up). The doctrine thus "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz*, 570 U.S. at 604.

Here, Janssen can continue to offer all 21 of its products in federal pharmaceutical markets only if it complies with the Program's requirements. *See* Chiesa Decl. Ex. A §§ 40.1, 40.6; *see also* 26 U.S.C. § 5000D(c). Even if that were a voluntary choice (it is not), the condition would still result in Janssen endorsing the Government's message and granting third parties a right to access its Xarelto® products on Government-dictated terms.

Those conditions are unconstitutional under both the First and Fifth Amendments.

As to Janssen's speech rights, the Government cannot condition governmental benefits "[b]y requiring recipients to profess a specific belief." *USAID v. All. for Open Soc'y Int'l*, 570 U.S. 205, 218–19 (2013). In *Alliance for Open Society International*, the Court struck down Congress's attempt to condition the receipt of federal funding on organizations "agree[ing] in the [funding] award document that [they are] opposed to prostitution and sex trafficking." *Id.* at 210. That condition was unconstitutional because the Government was "compelling a grant recipient to adopt a particular belief as a condition of funding … on an issue of public concern,"

inherently "affect[ing] protected conduct outside the scope of the federally funded program." *Id.* 218 (cleaned up).

Here, the Government seeks to condition Medicare and Medicaid participation on manufacturers like Janssen repeating its preferred message—that the Program involves nothing more than an "agreement" to "negotiate" "fair" prices. Yet such a condition would "by its very nature affec[t] protected conduct outside the scope of the federally funded program," making the condition inimical to the First Amendment. *Id.* That conclusion applies with special force here where the compelled speech has *nothing* to do with the Program itself: with or without the manufacturer's speech, Congress could still enact a statute setting the price of selected drugs. To be sure, the Government would lose the political cover of a manufacturer's forced agreement. But the First Amendment prohibits requiring manufacturers "to pledge allegiance to the Government's policy." *Id.* at 220.

As to Janssen's property rights in its Xarelto® products, conditioning a manufacturer's Medicare and Medicaid participation on the relinquishment of property rights is unconstitutional if the property demanded is either unconnected or not roughly proportional to the benefit sought. *Koontz*, 570 U.S. at 605–06. Here, the gross disproportionality is especially stark. If Janssen does not submit to the Program, it would be required not only to pull all Xarelto® products from Medicare Part D. It would have to withdraw *all* 21 of its drugs from *every* part of Medicare,

and from Medicaid as well. *See supra* pp. 11–12; 26 U.S.C. § 5000D(c). The Program's extension of its penalty against a manufacturer for refusing to accept *Medicare* pricing into the manufacturer's exclusion from *Medicaid* is a further unconstitutional condition. *See, e.g.*, *Harris v. McRae* 448 U.S. 297, 317 n.19 (1980) (a "substantial constitutional question would arise if Congress had attempted to withhold all Medicaid benefits" based on exercise of constitutional right).

Moreover, Janssen's noncompliance would not just affect its *future* participation in Medicare and Medicaid; it would undo Janssen's *existing* agreements for those programs. In *NFIB*, the Court rebuffed Congress's attempts to "penalize States that choose not to participate in that new program by taking away their existing Medicaid funding." 567 U.S. at 585. Likewise here, Congress cannot leverage existing reliance interests to attain its unconstitutional ends. There is no "reasonable relationship" between the supposedly voluntary condition and the participation rights afforded by Janssen's existing Medicare and Medicaid agreements. *See Dolan v. City of Tigard*, 512 U.S. 374, 395 (1994).

In short, even if the Program could be made "voluntary," the IRA would impose unconstitutional conditions on Janssen's participation in Medicare and Medicaid. Declaratory relief is thus appropriate to, among other things, allow Janssen to plan its business and protect the broader interest in safeguarding government benefits from unconstitutional conditions. *See Terra Nova*, 887 F.2d at 1224.

## CONCLUSION

Congress cannot achieve its goals "by a shorter cut than the constitutional way." *Horne*, 576 U.S. at 362 (quoting *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922) (Holmes, J.)). That principle applies with full force here. Longstanding precedent dictates that Congress may not pursue its goals in ways that violate regulated parties' constitutional rights.

For that reason and the others given above, the Court should grant summary judgment in favor of Janssen, declare that the Program violates the First and Fifth Amendments, and enjoin CMS from enforcing the Program's unlawful requirements (including any purported agreements that implement those requirements).

Respectfully submitted,

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